

EXHIBIT E

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1 purpose of the IFU?

2 A. The IFU is a document to provide some
3 general and some specific information to the
4 physician about the use of our product.

5 Q. Did you understand that the IFU is
6 considered under FDA regulations to be the
7 primary label for the medical device, in this
8 case, the PROLIFT?

9 A. Yes.

10 Q. And you understood this would be the
11 primary source of information that surgeons
12 would look to to get information with regard to
13 the safety and efficacy and potential risks of
14 using the PROLIFT with patients, correct?

15 A. When you say "primary," what do you
16 mean by "primary"?

17 Q. Meaning this would be the first --
18 well, rephrase.

19 When I say "primary," I say that
20 if -- if there was anything that a surgeon
21 would look at, it would be this, this would be
22 the first thing that they would look to?

23 A. I don't know if it's the first thing
24 that they would look to, because this would
25 have been part of our entire professional

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1 education package; so this would be one of the
2 things that they would look to, yes.

3 Q. Do you understand the significance
4 under FDA regulations of the IFU being the
5 primary label for the PROLIFT?

6 A. I understand the FDA regulations
7 around the document. I also understand the way
8 that physicians are trained and operate.

9 MR. SLATER: Move to strike from "I
10 also" forward.

11 BY MR. SLATER:

12 Q. What's your understanding as to the
13 significance of the IFU being the primary label
14 for the PROLIFT from FDA regulatory standpoint?

15 A. That the agency sees this as the
16 document that they review as a part of the
17 packaging for our materials. So it should
18 contain the relevant indications, description,
19 and -- and other pertinent information as
20 prescribed by the regulations.

21 Q. That would also include all necessary
22 contraindications, warnings and precautions,
23 and adverse reactions, correct?

24 A. It would include warnings,
25 precautions, contraindications, adverse

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1 reactions, sterility, disposal, storage,
2 et cetera.

3 Q. You have understood that all of the
4 information in the IFU needed to be accurate,
5 correct?

6 A. Yes.

7 Q. You understood that physicians were
8 going to rely on the IFU in making decisions
9 about whether or not to use the PROLIFT in
10 treating patients, correct?

11 MR. BROWN: Objection.

12 THE WITNESS: Physicians will not
13 rely solely on the IFU for making their
14 decisions. Physicians will use the IFU
15 to help inform them, but they will also
16 use other information.

17 BY MR. SLATER:

18 Q. You understood physicians would rely,
19 at least in part, on the PROLIFT IFU in making
20 decisions about whether they wanted to use that
21 product, that medical device, that system, in
22 their patients, correct?

23 MR. BROWN: Objection.

24 THE WITNESS: Physicians will use
25 this document and other documents to

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1 decide if they want to learn more about
2 the system, and ultimately will use
3 their training, education, and
4 experience, plus this document, to
5 decide if they want to use it.

6 BY MR. SLATER:

7 Q. Did you understand that it was
8 necessary to clearly and unambiguously
9 communicate all necessary contraindications,
10 warnings and precautions, and adverse reactions
11 to physicians through the IFU?

12 A. I understand the document should be
13 clear and unambiguous, yes.

14 Q. Did you understand that it was
15 necessary for Gynecare, to the extent that a
16 risk was understood to exist with the PROLIFT,
17 to communicate it in the IFU as opposed to
18 assuming that surgeons would figure out that
19 risk on their own?

20 A. I don't think you're giving surgeons
21 enough credit. Surgeons don't have to figure
22 out the complications of an area that they
23 operate. Surgeons are trained to know the
24 complications of the area in which they
25 operate.

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1 BY MR. SLATER:

2 Q. Does it mean too much tension?

3 A. It's not that simple.

4 Q. How would a surgeon doing the
5 procedure be able to objectively verify, based
6 on an objective standard, that they had placed
7 or not placed the mesh with excessive tension?

8 A. They would be able to look at the
9 repair after surgery and see if it looks
10 relaxed or see if it looks like it's under
11 tension.

12 Q. So that's how they would do it?

13 A. That's generally how it was done.

14 Q. Did you ever perform the PROLIFT
15 procedure?

16 A. On the cadavers, yes. In live
17 people, because I was not practicing during my
18 tenure at Ethicon, no.

19 Q. Did you ever on your own, without any
20 other surgeon performing the procedure -- did
21 you ever place Gynemesh in a human's body?

22 A. No.

23 Q. Look at the adverse reactions,
24 please. It was your understanding that you
25 needed to list each of the adverse reactions

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1 that were known to you in Medical Affairs in
2 this section, correct?

3 A. Yes.

4 Q. And you understood that if you failed
5 to list adverse reactions that you were aware
6 of, that that would render that warning
7 deficient to some extent, correct?

8 A. Deficient?

9 MR. BROWN: Objection.

10 THE WITNESS: I would say that we
11 listed the adverse reactions that we
12 knew were adequate and sufficient for
13 this document.

14 BY MR. SLATER:

15 Q. Well, you just said a moment ago you
16 agreed with me that you understood you were
17 supposed to list each of the adverse reactions
18 that you in Medical Affairs knew existed at the
19 time of launch, correct?

20 A. We listed the adverse events that we
21 knew to be directly related to the information
22 that we had at this time.

23 Q. Okay. Were there risks -- well,
24 rephrase.

25 You see where it says, at the end of